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Arizona State Board of Pharmacy

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New Board Members

The first quarter of each new year is, as usual, the time that Governor Janet Napolitano appoints new Arizona State Board of Pharmacy members to replace those members who have served admirably but whose terms have expired. In this age of term limits for public servants, it is always sad to see existing members go after what seems like such a short time, but it is part and parcel of living in our fast-paced, increasingly mobile society. The term for Paul Draugalis has expired. Paul served the Board and the citizens of the State of Arizona above and beyond the call of duty for the past five years. Mr Draugalis' dedication and insight will be missed. Shirley Thompson, who never actually had the opportunity to serve, resigned because of a family tragedy.

Ridge Smidt has been appointed to succeed Mr Draugalis. Mr Smidt is the long-time owner of Patient Care Infusion Pharmacy and he has practiced in this specialized area of pharmacy for many years. His insight into this specialized area will be very valuable as the Board deals with the issues of compounding and sterile products in the coming years.

Tom Van Hassel has been appointed and confirmed by the Senate to replace Shirley Thompson. Mr Van Hassel has been the director of pharmacy at the Yuma Regional Medical Center and was instrumental in purchasing and implementing a robotic dispensing system, which gave the Yuma Regional Medical Center pharmacy the distinction of being the first licensed hospital pharmacy in Arizona to utilize such a system. Mr Van Hassel's forward thinking will be an asset to the Board as it deals with pharmacy automation and electronic prescribing issues.

Dr Paul Sypherd has been appointed to succeed Mr Daniel Ketcherside. He is professor emeritus in the Department of Molecular and Cellular Biology at the University of Arizona (the UA) where he served as the senior vice president for academic affairs and provost, leaving that post in June 2000. Dr Sypherd received his bachelor of arts degree from Arizona State University in 1959 and a master of science degree in microbiology from the UA in 1960. He was awarded the PhD in microbiology from Yale University in 1963. Dr Sypherd has received international recognition for his research on bacterial nucleic acids and fungal molecular biology. As the UA chief academic officer, Dr Sypherd provided administrative leadership in improving undergraduate education through providing greater access to faculty, improvement of the general education curriculum, and career counseling. During Dr Sypherd's tenure as provost, the UA continued to mount strong research programs across the university, with the UA achieving the rank of 10th among American public universities in the rankings by the National Science Foundation.

Pharmacy Security and the Absence of a Pharmacist

It seems that every few years the issue of pharmacy security needs to be discussed in this *Newsletter*. With the recent licensure of pharmacy technicians, it is perhaps time to review the current Board rules dealing with this area of pharmacy law. Pharmacists should review the Arizona Administrative Code at the following link: www.azsos.gov/public_services/Title_04/4-23.pdf.

Rules R4-23-609 and 610 detail requirements for community pharmacy while R4-23-657 lists the requirements for hospital pharmacies. There are also rules for limited service pharmacies. Please do not hesitate to call your Board compliance officer for clarification of any of the existing rules. It is important to note that community pharmacies may not be entered or staffed unless a pharmacist is present at all times (except for certain rare emergency situations). This restriction has become even more important since the implementation of federal privacy laws concerning medical records has been put in place at the federal level. It is the joint responsibility of the pharmacist-in-charge and the

Continued on page 4

Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

Continued from page 1

permit holder to be aware of these rules and to strive for compliance with them.

It is also important to note that since May 2004, all pharmacy support personnel shall be licensed as either a technician trainee or pharmacy technician before working in that capacity in an Arizona pharmacy.

Recent Board Activities

By the time you receive this *Newsletter*, the Board will have attended a planning meeting to "brainstorm" about issues affecting the practice of pharmacy in Arizona and existing and proposed regulatory schemes that exist or might need to be developed to allow the Board to accomplish its mission of protecting the public. The meeting was held on March 16, 2005, at the Board offices and a summary of the issues discussed at the planning meeting will be available in the July edition of this *Newsletter* and online in the Recent Board Meeting Minutes section of our Web site, www.pharmacy.state.az.us/RECENTminutes.htm.

Disciplinary Actions – Board of Pharmacy (Actions Since November 2004 Board Meeting)

Notice: *Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).*

Rita Falcon-Smith, RPh – Censure, 15 hours of additional Continuing Education (CE) on pharmacy security or Controlled Substance record-keeping.

Disciplinary Actions – Other Health Care Practitioner Boards

Gary Stanford Blass, MD (#22064) – Summary suspension of license until further notice, effective February 17, 2005.

Edward W. Galapeaux, DDS (#2080) – Prohibition on prescribing CII or CIII Controlled Substances for one (1) year, additional CE, February 11, 2005.

Robert L. Berry, MD (#23069) – Unprofessional conduct in Washington State, summary suspension effective February 10, 2005.

Martin L. Burnett, MD (#14738) – Voluntary Cessation of Medical Practice until further notice, effective February 10, 2005.

Amalia Pineres, MD (#3829) – Letter of Reprimand, 10 hours CE and one (1)-year probation, effective February 10, 2005.

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